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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number	10/751,056	
	Filing Date	January 2, 2004	
JAN 2 9 2010 ()	First Named Inventor	Gerianne Tringali DiPiano	
	Group Art Unit	1628	
	Examiner Name	Jennifer M. Kim	
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Examiner Initials*	Cite No. ¹	Cite No. ¹	Cite No. ¹	Cite No. ¹	US Patent	t Document	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)						
	· -	3,921,636		Zaffaroni	11-25-1975				
		3,927,216		Witkowski, et al.	12-16-1975				
		4,081,533		Cheesman	03-28-1978	•			
		4,107,288		Oppenheim, et al.	08-15-1978				
		4,272,398		Jaffe	06-09-1981				
		4,286,587		Wong	09-01-1981				
		4,291,028		Vorys	09-22-1981				
		4,292,315		Vorys	09-29-1981				
		4,391,797		Folkman, et al.	07-05-1983				
	- 1 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2	4,524,359		Champagne	06-18-1985				
		4,525,340		Lange, et al.	06-25-1985				
		4,588,724		Greenway, III, et al.	05-13-1986				
	· · · · · ·	4,591,496		Cohen, et al.,	05-27-1986				
		4,673,405		Guittard, et al.	06-16-1987				
	• • • • • • • • • • • • • • • • • • • •	4,756,907		Beck, et al.	07-12-1988				
		4,762,717		Crowly, Jr.	08-09-1988				
		4,861,627		Mathiowitz, et al.	08-29-1989				

Examiner Cite No.1		Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office. ³	Number⁴	Kind Code ⁵ (if known)				
		EP	0 501 056		Igarashi, et al.	09-02-1992		
		EP	0 566 135		Takeda Chemical Industries	10-20-1993		
		GB	767 824		Organon Labor Ltd.	02-06-1957		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	10/751,056	
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	First Named Inventor	Gerianne Tringali DiPiano	
	Group Art Unit	1628	
	Examiner Name	Jennifer M. Kim	

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Attorney Docket Number

				U.S. PATENT DOCU	MENTS			
Examiner Initials*	Cite No. ¹			US Patent	Document	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)					
		4,873,092		Azuma, et al	10-10-1989			
		4,919,939		Baker	04-24-1990			
		4,965,128		Greidanus, et al.	10-23-1990			
	• • •	4,997,653		Igarashi, et al.	03-05-1991			
		5,057,317		lida	10-15-1991			
		5,091,185		Castillo, et al.	02-25-1992			
		5,130,137		Crowley, Jr.	07-14-1992			
		5,145,684	- · · · · · · · · · · · · · · · · · · ·	Liversidge, et al.	09-08-1992			
	·····	5,156,851		Castillo, et al.	10-20-1992			
		5,194,259		Soudant, et al.	03-16-1993			
		5,324,522		Krenning, et al.	06-28-1994			
		5,330,768		Park, et al.	07-19-1994			
		5,340,585		Pike, et al.	08-23-1994			
		5,359,030		Ekwuribe	10-25-1994			
		5,362,720		Labrie	11-08-1994			
		5,413,797		Khan, et al.	05-09-1995			

	 		F	FOREIGN PATENT DOCUMEN	ITS		
Examiner Cite Initials* No.1	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T [®]
	Office. ³	Number⁴	Kind Code ⁵ (if known)				
	PCT	WO 95/07071		Edko Trading and Representation Co.	03-16-1995		
	PCT	WO 95/31973		Eastman Kodak Co.	11-30-1995		
	PCT	WO 95/31974		Eastman Kodak Co.	11-30-1995		

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			First Named Inventor	Gerianne Tringali DiPiano	_
			Group Art Unit	1628	
			Examiner Name	Jennifer M. Kim	_
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				U.S. PATENT DOCU	MENTS	
xaminer Initials*	Cite No. ¹	US Paten	t Document	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		5,417,982		Modi	05-23-1995	
		5,434,146		Labrie	07-18-1995	
		5,438,040		Ekwuribe	08-01-1995	
		5,472,704		Santus, et al.	12-05-1995	
		5,482,925		Hutsell	01-09-1996	
		5,482,927		Maniar, et al.	01-09-1996	
		5,494,047		Van Os	02-27-1996	
		5,510,118		Bosch, et al.	04-23-1996	
		5,536,499		Znaiden, et al.	07-16-1996	
	_	5,552,160		Liversidge, et al.	09-03-1996	
	•	5,633,011		Dong, et al.	05-27-1997	
		5,643,604		Angeles Uribe, et al.	07-01-1997	
		5,651,976	-	Price, et al.	07-29-1997	
		5,705,170		Kong, et al.	01-06-1998	
		5,778,894		Dorogi, et al.	07-14-1998	
· · · · · · · · · · · · · · · · · · ·		5,789,442		Garfield, et al.	08-04-1998	
· · · · · · · · · · · · · · · · · · ·		5,843,509		Calvo Salve, et al.	12-01-1998	
		5,945,109		Schmidt, et al.	08-13-1999	

			· 	F	OREIGN PATENT DOCUMEN	ITS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	•	T ⁶
		Office.3	Number⁴	Kind Code ⁵ (if known)	5			į
		PCT	WO 96/00567		Eastman Kodak Co.	01-11-1996		
		PCT	WO 96/25150		Nanosystems LLC	08-22-1996		

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		ATEME	TION DISCLOSURE NT BY APPLICANT	Application Number	10/751,056		
		(use as ma	any sheets as necessary)	Filing Date	January 2, 2004		
				First Named Inventor	Gerianne Tringali DiPiano		
				Group Art Unit	1628		
				Examiner Name	Jennifer M. Kim		
		of	. 9	Attorney Docket Number	FEM 104		

		·	U.S. PATENT DOCU	MENTS	
Examiner Initials*	Cite No. ¹	US Patent Document	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code (if known)			·
		6,071,526	Schmidt, et al.	06-06-2000	
	,	6,087,351	Nyce	07-11-2000	
		6,358,539	Murad	03-19-2002	
		6,436,428	Mahashabde, et al.	08-20-2002	
		6,517,864	Orup Jacobsen, et al	02-11-2003	
		6,743,441	Sanders, et al.	06-01-2004	
		6,908,623	Deaver, et al.	06-21-2005	
		2002/0150605	Yui, et al.	10-17-2002	
· 		2003/0109507	Franke, et al.	06-12-2003	
	_	2003/0143278	DiPiano, et al.	07-31-2003	
		2003/0175329	Azarnoff, et al.	09-18-2003	
	<u> </u>	2004/0002503	Chang, et al.	01-01-2004	
		2005/0101579	Shippen	05-12-2005	
		2008/0153789	Dmowski, et al.	06-26-2008	
		2008/0299207	Martin	12-04-2008	
	-	12/497,865	DiPiano, et al.	07-06-2009	

	•••			F	OREIGN PATENT DOCUMEN	ITS		
Examiner Initials*	Cite No. ¹		Foreign Patent Doc	ument	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ°
		Office.3	Number⁴	Kind Code⁵ (if known)				
		PCT	WO 96/37232		Universidade de Santiago de Compostela (ES)	de 11-28-1996		
		PCT	WO 98/11888		American Home Prod.	03-26-1998		
		PCT	WO 99/24041		Cellegy Pharma Inc.	05-20-1999		

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	STA	TEME	TION DISCLOSURE NT BY APPLICANT	Application Number	10/751,056	
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				First Named Inventor	Gerianne Tringali DiPiano	
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	U.S. PATENT DOCUMENTS									
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		PCT	WO 02/17926		Unimed Pharma Inc.	03-07-2002		
		PCT	WO 03/039553		Pharmacia Corporation	05-15-2003		
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				First Named Inventor	Gerianne Tringali DiPiano	
				Group Art Unit	1628	
				Examiner Name	Jennifer M. Kim	
T	6	of	9	Attorney Docket Number	FEM 104	

· · · ·	······································	OTHER ART NON PATENT LITERATURE DOCUMENTS
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
		AKIO, "Danazol Suppository", Patent Abstracts of Japan 15(263): (C-0847) (1991).
		ANDERSON, et al., "Once daily controlled versus immediate release oxybutynin chloride for urge urinary incontinence. OROS Oxybutynin Study Group," <i>J. Urol.</i> 161: 1809-1812 (1999).
;		BARNHART, et al., "Distribution of a spermicide containing Nonoxynol-9 in the vaginal canal and the upper female reproductive tract", <i>Hum Reprod</i> ,.16(6):1151-4 (2001).
		BENITA, et al., "Characterization of drug-loaded poly(d,l-lactide) microspheres," J Pharm Sci 73(12): 1721-1724 (1984).
		BRAUN, et al., "Effect of danazol in vitro and in vivo on monocyte-mediated enhancement of endometrial cell proliferation in women with endometriosis," Fertility and Sterility 62(1): 89-95 (1994).
		BRENDLER, et al., "Topical oxybutynin chloride for relaxation of dysfunctional bladders," J. Urol. 141(6): 1350-52 (1989).
		BUYSE, et al., "Intravesical oxybutynin for neurogenic bladder dysfunction: less systemic side effects due to reduced first pass metabolism," <i>J. Urol.</i> 160: 892-896 (1998).
		CICINELLI, et al., "First uterine pass effect is observed when estradiol is placed in the upper buy not lower third of the vagina", Fertility and Steriility, 81(5):1414-1416 (2004).
		COMER & GOA, "Extended-release oxybutynin," <i>Drugs Aging</i> 16: 149-155 (2000).
		DAS NEVES, et al., "Gels as vaginal drug delivery systems", Int. J. Pharm. 2:318(1-2):1-14 (2006) Epub 2006 Mar 17.
		DE ZIEGLER, et al., "Administration non-orale de la progestérone: Expériences et avenir de la voie transvaginale," Rev. Med. Suisse Romande pp. 13-28 (1994) (with English abstract).
		FARQUHAR, et al., "Management of dysfunctional uterine bleeding," Drugs 44(4): 378-384 (1992).

Examiner's	Date Considered	
Signature		

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	(use as r	nany sheets as necessary)	Filing Date	January 2, 2004	
			Filing Date First Named Inventor	Gerianne Tringali DiPiano	
			Group Art Unit	1628	
			Examiner Name	Jennifer M. Kim	
	of	9	Attorney Docket Number	FEM 104	

	•	OTHER ART NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T*
		FEMMEPHARMA, "FP1096-001 Executive Summary," (2004).	
	1	FINNIN and MORGAN, "Transdermal penetration enhancers: applications, limitations, and potential", <i>J. Pharm. Sci.</i> , 88(10):955-8 (1999).	
	1	GERAGHTY, et al., "The in vitro release of some antimuscarinic drugs from monoolein/water lyotropic crystalline gels," <i>Pharm. Res.</i> 13(8): 1265- 1271 (1996).	
		GOLDENBERG, "An extended-release formulation of oxybutynin chloride for the treatment of overactive urinary bladder," Clin. Ther. 21(4): 634-642 (1999).	
- 100		GUPTA & SATHYAN, "Pharmacokinetics of an oral once-a-day controlled-release oxybutynin formulation compared with immediate-release oxybutynin," <i>J. Clin. Pharmacol.</i> 39: 289-296 (1999).	
		GUERRIERO, et al., "Influence of vaginal danazol on uterine and brain perfusion during hormonal replacement therapy", Menopause, 8(6); 424-428 (2001) (abstract only).	
		HULL, et al., "Endometriosis: An enigmatic disease," <i>J Women's Health</i> 5(2): 111-120 (1996).	
		IGARASHI, "A new therapy for pelvic endometriosis and uterien adenomysosis: Local effect of vaginal and intrauterine danazol application," Asia-Oceania J. Obstet. Gynaecol. 16(1): 1-12 (1990).	
		LIM, et al., "Microencapsulation of living cells and tissues," J Pharm. Sci. 70(4): 351-354 (1981).	
		LIVERSIDGE, et al., "Particle size reduction for improvement of oral bioavailability of hydrophobic drugs: I. Absolute oral bioavailability of nanocrystalline danazol in beagle dogs", Int J Pharm., 125:91-97 (1995).	
		LOBO, et al., "Vaginal route paradox: A direct transport to the uterus," Symposium: The First Uterine Pass Effect, Wyeth-Ayerst International, Inc. (1995).	
		MASSAD, et al., "The pharmacokinetics of intravesical and oral oxybutynin chloride," J. Urol. 148: 595-597 (1992).	
	<u> </u>		

Examiner's	Date Considered	
Signature		

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	•	First Named Inventor	Gerianne Tringali DiPiano	
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		OTHER ART NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	7
		MATHIOWITZ, et al., "Morphology of polyanhydride microsphere delivery system," Scanning Microscopy 4(2): 329-340 (1990).	
		MATHIOWITZ, et al., "Novel microcapsules for delivery systems," Reactive Polymers 6: 275-283 (1987).	
		MATHIOWITZ, et al., "Polyanhydride microshperes as drug carriers I. Hot-melt microencapsulation," <i>J Controlled Release</i> 5:13-22 (1987).	-
		MATHIOWITZ, et al., "Polyanhydride microspheres as drug carriers. II. Microencapsualtion by solvent removal," <i>J Appl. Polymer Sci.</i> 35: 755-774 (1988).	
		MIZUTANI, et al., "Danazol concentration in ovary, uterus, and serum and their effect on the hypothalamic-pituitary-ovarian axis during vaginal administration of a danazol suppository," Feritility and Sterility 63(6): 1184-1189 (1995).	
		Physicians' Desk Reference, Consult 1994 Supplements for Revisions, pp. 1372-1375.	
		RAMJEE, et al., "Acceptability of Carraguard, a candidate microbicide and methyl cellulose placebo vaginal gels among HIV-positive women and men in Durban, South Africa", AIDS Res Ther. 4:20 pp.1-10 (2007).	
		SAITO, et al., "Treatment of overactive bladder with modified intravesical oxybutynin chloride," Neurol. Urodyn. 19: 683-688 (2000).	
<u>.</u>		SALIB, et al., "Utilization of sodium alginate in drug microencapsulation," Pharmazeutische Industrie 40(11A): 1230-1234 (1978).	
		SCHRÖDER, et al., "Absorption of oxybutinin from vaginal inserts: drug blood levels and the response of the rabbit bladder," Urology 56(6): 1063-1067 (2000).	
		SPOONER, Classification of Side Effects to Danazol Therapy, Winthrop Laboratories, Surrey, England.	

Examiner's	Date Considered
Signature	

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Jennifer M. Kim

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· ·	Group Art Unit	1628

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	<u> </u>	"Sultrin," Physicians' Desk Reference, 51st ed., pp. 1941 (1997).	
		TAKEBAYASHI, et al., "Danazol suspension injected into the uterine cervix of patients with adenomyosis and myoma. Preliminary study", <i>Gynecol. Obstet. Invest.</i> , 39(3):207-11 (1995) (abstract only).	
		"Terazol 7," Physicians' Desk Reference, 51st ed., pp. 1943 (1997).	
		The First Uterine Pass Effect – A new finding for new options in progesterone therapy, West-Ayerst Internation, Inc., pp 1-2 (1995).	,
		THÜROFF, et al., "Randomized, double-blind, multicenter trial on treatment of frequency, urgency and incontinence related to detrusor hyperactivity: oxybutynin versus propantheline versus placebo," <i>J. Urol.</i> 145: 813-816 (1991).	
		VERSI, et al., "Dry mouth with conventional and controlled-release oxybutynin in urinary incontinence," Obstet Gynecol. 95(5): 718-721 (2000).	
		WAGNER, et al., "The novel progesterone receptor antagonists RTI 3021-012 and RTI 3021-022 exhibit complex glucocorticoid receptor antagonist activities: implications for the development of dissociated antiprogestins", Endocrinology, 140(3):1449-58 (1999).	
		WELLBERY, et al., "Diagnosis and treatment of endometriosis", Am. Fam. Physician, 60:1753-68 (1999).	
		WOLTHERS KLUWER HEALTH, INC., "Summary Review: Oxybutynin Chloride 10 % Gel", Wolthers Kluwer Health, Inc., (2009).	
		YAMASHITA, et al., "Immunohistochemical determination of endometrial progesterone receptor (PR) content after intrauterine infusion of danazol in rabbits", Nippon Naibunpi Gakkai Zasshi, 69(10):1044-1050 (1993) (abstract only).	
		ZHANG, et al., "Synthesis and progesterone receptor antagonist activities of 6-aryl benzimidazolones and benzothiazolones", Bioorg. Med. Chem. Lett., 11(20):2747-50 (2001).	

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